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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,043	04/12/2004	Barrie Tan	BT-001	4102

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EXAMINER	
MCCORMICK EWOLDT, SUSAN BETH	
ART UNIT	**PAPER NUMBER**
1661	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,043	TAN ET AL.	
	Examiner	Art Unit	
	S. B. McCormick-Ewoldt	1661	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,25 and 37-56* is/are pending in the application.

4a) Of the above claim(s) *51-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,25 and 37-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment of January 3, 2007 is hereby acknowledged and entered.

Election/Restrictions

Applicant elected, without traverse, Group I and the species, palm extract, in the reply filed on July 21, 2005.

Newly submitted claims 51-56 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 51-56 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims Pending

Applicant has cancelled claims 2-24, 26-36. Applicant has added claims 51-56. Claims 1, 25 and 37-50 will be examined on the merits and solely in regards to the elected species. Claims 51-56 are withdrawn.

Specification

The amendment filed January 2, 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: see newly added Table 1.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39, 47 and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is over the recitation "a 350-450 Dalton MW fraction of". Applicant has amended the specification (i.e. see Table 1) by incorporating the molecular weights of alpha, beta, gamma and delta tocopherols and tocotrienols. Thus, an attempt to limit molecular weights of tocotrienols and tocopherols adds new matter. The specification does not disclose the molecular weights of tocotrienols and tocopherols; thus, these limitations may introduce new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39, 47 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In claims 39, 47 and 49, the recitation "fraction of a natural extract" is indefinite because it is not clear what is encompassed by this recitation. How can there be a "fraction" of an extract? Clarification is needed.

In claim 47, the term "comprsing" is misspelled. Correction is needed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill

in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 25, 37-50 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tan (US 6,350,453) in view of Wright (US 5,217992) further in view of Meijer *et al.* (US 6,787,151) for reasons set forth in the previous Office action which are restated below. Applicant's arguments filed January 3, 2007 have been fully considered but they are not persuasive.

Tan (US 6,350,453) disclose that a *Bixa orellana* (i.e. annatto) oil byproduct (column 5, lines 51-55) and a natural extract (i.e. vegetable oil) is added and thru a distillation process tocotrienols are 20-90% by weight (column 4, lines 33-37; column 5, lines 30-42). Tan teaches that there is essentially no tocopherol present in this distillate (column 2, lines 46-48). In addition, Tan discloses tocopherols and tocotrienols act as antioxidants and tocotrienols have been documented to possess hypocholesteromic effects and to be useful in the treatment of cardiovascular disease and cancer (column 1, lines 10-46).

Tan does not disclose wherein the amounts are disclosed for the tocotrienols and tocopherols or wherein palm oil is specifically use together with the *Bixa orellana* extract.

Wright (US 5,217992) discloses that palm oil is a rich source of tocotrienols such as gamma-tocotrienols and delta-tocotrienols, which are known to treat hypercholesteremia, hyperlipedemia an thromboembolic disorders (column 1, lines 12-15; column 3, lines 21-27; column 4, lines 23-33).

Meijer *et al.* (US 6,787,151) disclose that phytosterols and soy protein are well documented to have a hypocholesterolmic effect (column 1, lines 29-30 and 39-41). In addition, other ingestable materials as causing improvement in cholesterol status include niacin, tocotrienols, chromium, soy, lecithin and chitosan (column 2, lines 43-49).

One of ordinary skill in the art would have been motivated to combine *Bixa orellana* (i.e. annatto) oil byproduct and a palm oil extract (i.e. natural extract) because of the beneficial properties that tocotrienols have in decreasing blood levels and the various types of tocotrienols would be inherent to the extract. It was clear from the Tan reference that *Bixa orellana* (i.e. annatto) oil byproduct and a natural extract (i.e. vegetable oil) is added together and thru a distillation process, tocotrienols amounts are 20-90% by weight. Tan also discloses that there is

essentially no tocopherol present in this distillate. In addition, Tan discloses tocopherols and tocotrienols act as antioxidants and tocotrienols have been documented to possess hypocholesteromic effects and to be useful in the treatment of cardiovascular disease and cancer It was further clear from the Wright reference that palm oil is a rich source of tocotrienols, such as gamma-tocotrienols and delta-tocotrienols, which are known to treat hypercholesteremia, hyperlipedemia an thromboembolic disorders. It was further clear from the Meijer reference that phytosterols and soy protein are well documented to have a hypocholesterolmic effect and other ingestable materials to cause improvement in cholesterol status include niacin, tocotrienols, chromium, soy, lecithin and chitosan. It would clearly have been obvious to one of ordinary skill in the art to adjust the amounts of tocotrienols and tocopherols as taught by the cited reference because the references clearly disclose that such preparations is intended to be administered so as to achieve the therapeutic effect beneficially disclosed by the references. The adjustment of particular conventional working conditions (e.g., determining a result-effective amount) is deemed merely a matter of judicial selection and routine optimization, which is well within the purview of the skilled artisan.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions to treat hypocholesteromic effects. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re* Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re* Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re* Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in compositions for treating hypocholesteromic effects, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions decreasing treat hypocholesteromic effects. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition because of the beneficial properties that tocotrienols contain. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re* Sussman, 1943 C.D. 518; *In re* Huellmantel 139 USPQ 496; *In re* Crockett 126 USPQ 186.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the cited reference.

Therefore, one of ordinary skill in the art would have had a reasonable expectation that Bixa orellana byproduct and palm oil and phytosterols, soy proteins, niacin, tocotrienols, chromium, soy, lecithin and chitosan can be combined in a composition which would treat hypocholesteromic effects and contain the various type of tocotrienols. Based on this reasonable expectation of success, a person of ordinary skill in the art would be motivated to modify the teachings of the references.

Applicant's arguments concerning the above art rejection have been fully considered but are not deemed to be persuasive.

Applicant argues that in light of the amendments made to the claims that these cited references do not disclose all limitations of the claims. This is not found persuasive. With regard to the Tan reference even though Tan does not disclose specifically the ratios and/or levels of tocopherol and tocotrienols it would clearly have been obvious to one of ordinary skill in the art to adjust the ratios and/or levels of tocotrienols and tocopherols for the adjustment of particular conventional working conditions (e.g., determining a result-effective amount) is deemed merely a matter of judicial selection and routine optimization, which is well within the purview of the skilled artisan. With regards to the Meijer reference, the ingredients include carnitine, magnesium, calcium and vitamins B5, B6, and B12 are disclosed as such (see col. 2, lines 47-48; col. 9, lines 63-66). In the Wright reference, palm oil (i.e. natural extract) is disclosed (see col. 3, line 23).

Therefore, the rejection is deemed proper and is maintained.

Summary

No claim is allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

CHRISTOPHER R. TATE
PRIMARY EXAMINER